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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
OWENS JR, HOWARD V	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/048,034	SHEPARD, H MICHAEL	
	Examiner	Art Unit	
	Howard V Owens	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *14-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) *14-16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Objections

Claims 14-16 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have/has not been further treated on the merits.

Claim 1 appears to be missing the term "agent" after the term "infectious" on line 2.

Claim 14 appears to contain the term "claims" repetitively.

Abstract Missing

This application does not contain an Abstract of the Disclosure as required by 37 C.F.R. § 1.72(b). An Abstract on a separate sheet is required.

IDS

Applicant should note that non patent literature and foreign documents were submitted with this application; however, a copy of the information disclosure statement reflecting these documents was not submitted.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 13, 18 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Griengl et al., J. Med. Chem., Vol. 31(9), 1988, pages 1831-1839.

Claim 1 is drawn to a method of inhibiting the proliferation of an infectious agent via administration of a compound that is converted to a toxin by the activating enzyme of the infectious agent.

Dependent claims 2 and 3 are drawn to the sugar linked or carbocyclic linked 5- substituted heterocyclic prodrug compound. Dependent claims 4 – 8 and 13 are drawn to the enzyme being thymidylate synthase and contacting in vitro/in vivo. Dependent claims 10-12 are drawn to the use of an assay to determine the inhibition of the infectious agent.

Dependent claims 18 and 19 are drawn to the method wherein the activating enzyme is a mutant that is resistant to therapy.

Griengl anticipates these claims as it teaches the administration of a sugar linked uridine prodrug compound in the form of a 5-substituted 2' deoxyuridine for the inhibition of herpes simplex 1 virus (HSV-1). Griengl also teaches the use of these compounds in vivo and in vitro (p. 1834), with an accompanying assay, wherein thymidine kinase is present or absent (therapy resistant form - p. 1834, paragraph 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-19 are rejected under 35 U.S.C. § 103 as being unpatentable over Griengl et al., J. Med. Chem., Vol. 31(9), 1988, pages 1831-1839.

Claim 1 is drawn to a method of inhibiting the proliferation of an infectious agent via administration of a compound that is converted to a toxin by the activating enzyme of the infectious agent.

Dependent claims 2 and 3 are drawn to the sugar linked or carbocyclic linked 5- substituted heterocyclic prodrug compound. Dependent claims 4 – 8 and 13 are drawn to the enzyme being thymidylate synthase and contacting in vitro/in vivo.

Dependent claims 18 and 19 are drawn to the method wherein the activating enzyme is a mutant that is resistant to therapy.

Dependent claim 9 is drawn to the use of a second infectious agent.

Griengl anticipates these claims as it teaches the administration of a sugar linked uridine prodrug compound in the form of a 5-substituted 2' deoxyuridine for the inhibition of herpes

simplex 1 virus (HSV-1). Griengl also teaches the use of these compounds in vivo and in vitro (p. 1834), wherein thymidine kinase is present or absent (therapy resistant form - p. 1834, paragraph 1).

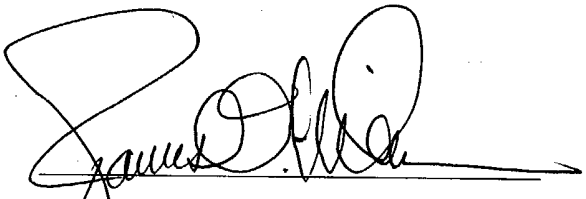
It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use a second agent to inhibit the proliferation of the infectious agent.

A person of ordinary skill in the art would have been motivated to use a second agent to inhibit the proliferation of an infection to either treat an infection that is more resistant to the first agent or to reduce the dosage associated with the administration of the first agent.

Allowable Subject Matter

The prior art of record does not teach or fairly suggest the use of the prodrug compounds for the treatment of HIV resistant to AZT therapy as set forth in claim 20 of the instant claims.

Howard V. Owens
Patent Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.